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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,552	08/02/2001	Hideakira Yokoyama	0020-4883P	4627
2292	7590	09/21/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			KRASS, FREDERICK F	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 09/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,552	Applicant(s) YOKOYAMA ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,20 and 22-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,22,23 and 26 is/are allowed.
- 6) ☒ Claim(s) 20, 24, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

5.0.2

Previous Rejections

Unless maintained infra, all previous rejections are withdrawn.

Obviousness Rejection (New)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rucker ("Mint Oil Reduces Headaches", Translation of relevant parts of XP-001157330) in view of Hipkind et al (USP 5,792,760).

The primary reference discloses the use of peppermint oil in liquid form to reduce headache pain, by applying 10ml of a 10% solution to the forehead and temple, dividing the total dose into three single subdoses which are applied with an interval of 15 minutes between each. The reference states what is well-known in the art, namely that peppermint oil contains (l-) menthol as a main active component. It also states that peppermint oil "reduces headaches because it inhibits the effect of the two messengers serotonin and Substanz P", but differs from the instant claims insofar as it discloses the treatment of tension headaches, while remaining silent regarding migraines. (Note that the instantly rejected claims are read upon by the administration of peppermint oil alone, since when the oil is administered its active ingredient (menthol) is simultaneously administered as well. The claims as currently written do not provide any clear line of demarcation, e.g. specific proportions, between the menthol active ingredient and the oil

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which carries it. Note also that claim 20 has been amended to remove the term "synergy" which, as discussed in the previous Office action, had implicitly required two separate components).

The secondary reference teaches that substance P is involved in the neurotransmission of pain sensations, including the pain associated with migraine headache, and thus can be treated with a substance P inhibitor. See col. 2, lines 32-43; col. 4, lines 20 and 21; col. 32, lines 55-66 and col. 44, lines 52 et seq. A preferred route of administration for the substance P inhibitor is transdermal, via patches to provide continuous or discontinuous infusion in controlled amounts. See col. 48, lines 3-12. The secondary reference differs from the instant claims, however, in that it discloses particular bisindoles as substance P inhibitors, rather than menthol as claimed instantly.

Since peppermint oil (l-menthol) is a substance P inhibitor as disclosed by the primary reference, it would have been obvious to have used it to treat migraine headaches as taught by the secondary reference. The motivation to do so would arise from sound scientific reasoning and the natural desire of physicians to expand the use of known therapies to as many patients as would reasonably be expected to benefit therefrom. Regarding instant claim 24, it would have been obvious to have used a patch to administer the topical liquids of the primary reference, motivated by the desire to provide improved control over administration as taught by the secondary reference.

2) Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rucker ("Mint Oil Reduces Headaches", Translation of relevant parts of XP-001157330) in view of Hipskind et al (USP 5,792,760), the combination being taken further in view of Deans et al (USP 5,858,370).

The primary and secondary references, and the rationale for combining their teachings, are discussed in subsection "1)" supra. The combined teachings of the primary and secondary references differ from the instant claim insofar as no mention is made of lavender, juniper, rose or rosemary oil.

The tertiary reference teaches that essential oils of various plants, including rosemary and peppermint (see Table 1.3, bridging the bottom of cols. 13 and 14), are able to combat changes in the level of neuropeptides in nervous tissue (col. 1, lines 27 and 28) generally, and are substance P inhibitors

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more specifically (col. 2, lines 34-37). The reference differs from the instant claims insofar as it does not specifically teach the treatment of migraine headaches.

It is well-settled that it is obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In re Kerkhoven, 205 U.S.P.Q. 1069 (CCPA 1980). The idea for combining said compositions flows logically from their having been individually taught in the prior art. In re Crockett, 126 USPQ 186, 188 (CCPA 1960). Accordingly, it would have been obvious to have combined peppermint oil, a substance P inhibitor used to treat migraine as suggested by the combined teachings of the primary and secondary references, with rosemary oil, also known to be a substance P inhibitor from the tertiary reference, for the very same purpose of inhibiting substance P and treating migraine as motivated by the guidance provided by the reasoning of the cited precedent.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

